

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

Status of the Claims

Claims 1-19 are presented. Claims 1, 15-16 and 18-19 are amended for clarity. Claim 1 is also amended to specifically claim the efficiency improvements of applicants' process. Support is found throughout the specification as originally filed. No claims are cancelled. No new claims are added.

No new matter has been introduced.

Summary of the Invention as Claimed

One aspect of the invention as now claimed is drawn to a process for isolating and purifying phytosterols and phytostanols from tall oil pitch comprising steps a) through k). In particular predistilling, step b), and neutralizing to a pH in the range of 5.8-6.3, step d), are critical to applicants' process, wherein step b) improves efficiency by reducing the amount of base require in step c) thereby reducing the amount of acid required in step d); and wherein the step d) neutralization to a pH of 5.8-6.3 improves efficiency by facilitating water removal in subsequent steps and by minimizing reesterification of the free sterol and/or stanol (claim 1).

Rejections under 35 U.S.C. § 103(a)

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as being obvious over Wong et al. (WO 99/42471, "Wong"). Applicants respectfully traverse the rejection.

Wong discloses a method of preparing phytosterols from tall oil pitch containing sterol esters, comprising the steps of (a) converting the sterol esters to free sterols, (b) removing light ends by evaporation, (c) evaporating the resulting bottom fraction to produce a light phase distillate, (d) dissolving in an alcoholic solvent, (e) cooling, and (f) washing and filtering to isolate crystalline

phytosterols. Step (a) preferably comprises (i) saponifying with alkali, (ii) neutralizing with acid, and (iii) heating to remove water.

Although applicants do not necessarily agree with the Examiner's characterizations of Wong, applicants respectfully suggest that the Examiner has failed to appreciate the key differences distinguishing the pending claims from the disclosure of Wong. Applicant's goal is to provide an economically viable and competitive process for producing free sterols/stanols from tall oil pitch. The economic factors are closely tied to the efficiency of the entire process, as represented by the efficiency of each individual step. Broadly, the issues to be addressed are (1) the efficient conversion of sterol/stanol esters to free sterols/stanols (and by corollary, to prevent their reesterification), and (2) efficient isolation from the pitch matrix.

To this end, applicants have first discovered that a predistillation of tall oil pitch to remove volatile acidic components is critical to the economic viability of the process. This reduces the necessary inputs of both base for saponification, as well as acid for subsequent neutralization in the following steps. Second, applicants have discovered that neutralization to a critically narrow pH range preserves sterols/stanols in the modified pitch by minimizing reversion to sterol/stanol esters via acid-catalyzed reesterification. Neutralization to the critical pH range further facilitates water removal in subsequent steps.

There is neither teaching, suggestion, nor motivation in Wong for either of these economically critical steps.

Further, other distinctions between applicants' now-pending claims and Wong include a separation period of at least 12 hours (vs. Wong's 2 hours), applicants' specified water content of <15% (vs. Wong's Example showing 37.5%) before vacuum stripping of remaining water, and crystallization from a solvent comprising low molecular weight acetate esters, ketones, and/or hydrocarbons. These also improve the economic viability of the process over Wong.

In summary, applicants' process as presently amended is patentably unobvious over the cited art.

Conclusion

In view of the above claim amendments and remarks, applicants believe that all of the pending claims as amended are in condition for allowance. The Examiner is respectfully requested to reconsider, withdraw the rejections and allow the claims.

If any additional fees are required in support of this application, authorization is granted to charge our Deposit Account No. 50-1943.

Respectfully submitted,

December 17, 2009

/Robert N. Henrie II/
Robert N. Henrie II
Registration No. 60,851
Fox Rothschild LLP
2000 Market Street; 20th Floor
Philadelphia, PA 19103-3222
Tele: (215) 299-2000
Fax: (215) 299-2150